

### REMARKS/ARGUMENTS

The rejections presented in the Office Action dated November 29, 2006 (hereinafter Office Action) have been considered. Claims 1-15, 24-42, 44-48, and 50-54 remain pending in the application.

Claims 1, 24, 44, 45, 50, and 51 are amended. Independent claims 1 and 24 were each amended to include subject matter from now canceled claims 43 and 49. Dependent claims 44, 45, 50, and 51 were amended to reflect the amendments to claims 1 and 24. Accordingly, no new matter has been added.

The Applicant acknowledges the indication of allowable subject matter of claims 9, 10, 38 and 39.

Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The Applicant respectfully submits that the present responsive amendment should be entered and considered, because the Examiner has previously searched and considered the features of canceled claims 43 and 49 (now incorporated into base claims 1 and 24) in the prior Office Action. Hence, the Applicant submits that the present responsive amendment does not necessitate a new search or further consideration that would present an undue burden to the Examiner. In the present responsive amendment, the Applicant traverses the prior basis for rejecting the claims, particularly claims 43 and 49, and presents arguments that are believed to overcome the rejections of record and place the claims in condition for allowance.

Claims 1, 2, 8, 15, 24-31, 37 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to *Niazi* (hereinafter "*Niazi*") in view of U.S. Patent No. 4,586,923 to *Gould et al.* (hereinafter "*Gould*") and U.S. Patent No. 6,408,214 to *Williams et al.* (hereinafter "*Williams*").

Claims 43-45 and 49-51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Niazi* in view of *Gould* and *Williams* as applied to claims 1 and 24, and further in view of U.S. Patent No. 5,462,527 to *Stevens-Wright et al.* (hereinafter "*Stevens*").

Independent claims 1 and 24 are amended to include subject matter from dependent claims 43 and 49, respectively. In the Office Action, the Examiner concedes that *Niazi, Gould* and *Williams* do not teach the limitations of former dependent claims 43 and 49. (Page 7). In the §103(a) rejection of dependent claims 43 and 49, the Examiner relies on the *Stevens* reference to modify the device of *Niazi* in view of *Gould* and further in view of *Williams* to include a steering lever retention mechanism. (*Id.*).

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. The Applicant respectfully traverses the rejections since all claim elements are not taught or suggested by the combination, and there would be no motivation to combine the references, nor a reasonable likelihood of success for the combination, as proposed by the Examiner.

The Applicant's amended independent claims 1 and 24 each recite, among other feature, some variation of a retention mechanism provided on the guide handle to retain the steering lever at a fixed position.

*Stevens* discloses an elongated flexible shaft 10 that is steerable by rotation of a thumb wheel 92 with an integrally formed pulley 96 as part of a handle 12 connected with the elongated flexible shaft 10. (Col. 5, Lines 14-19; Col. 6, Lines 56-64; Col. 8, Lines 54-61). Rotation of the thumb wheel 92 rotates the pulley 96 and provides tension on cables 32a and 32c, which deflects a portion of the shaft 10. (Col. 4, Lines 14-27; Col. 5, Lines 14-19; Fig. 5). A controlled amount of friction is imparted to the circular thumb wheel 92 by a coaxially positioned compressing O-ring 114, which creates rotational resistance to maintain the thumb wheel 93 in a particular position. (Col. 9, Lines 27-34, Fig. 14).

The Applicant respectfully submits that *Stevens* does not disclose a lever retention mechanism, but only a wheel friction mechanism. Considering that *Stevens* relies on the compressing O-ring 114 to provide a compressing force circumferentially about the axis on

which the thumb wheel 92 rotates to provide sufficient friction to arrest motion of the steering mechanism, there is no reasonable expectation that this same mechanism would work with a lever instead of a wheel.

As such, the Applicant respectfully submits that there would be no reasonable expectation of success of combining *Gould's* steering lever with *Stevens'* wheel bracing mechanism that requires annular friction provided by an O-ring. As such, the proposed combination of teachings from the *Niazi*, *Gould*, and *Stevens* references cannot be used to support a § 103(a) rejection of the Applicant's claims. (MPEP § 2142).

Further, the *Stevens* apparatus requires the entirety of the circumferential contacting surface areas (e.g., 360 degrees) of the thumb wheel 92 and O-ring 114 to provide the requisite rotational resistance to the thumb wheel 92. In contrast, employment of Applicant's steering lever apparatus eliminates the need for such circumferential contacting surfaces, yet provides for retention of the steering lever at a fixed position. It is well recognized that the omission of an element (e.g., the entirety of *Stevens'* circumferential contacting surfaces) and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966).

Moreover, despite *Gould's* disclosure of a steering lever and *Steven's* wheel bracing mechanism, the Applicant respectfully submits that neither *Gould* nor *Stevens* teaches or suggests, alone or in combination, a steering lever retention mechanism. Even if there was a proper likelihood of success and motivation in combining *Gould's* steering lever and *Steven's* wheel bracing mechanism, this combination of teachings still does not yield a steering lever retention mechanism.

The Applicant's amended independent claims 1 and 24 each recite some variation of a retention mechanism provided on the guide handle to retain the steering lever at a fixed position, which is not taught or suggested by *Niazi*, even in combination with *Gould*, in further combination with *Williams*, and in further combination with *Stevens*. Therefore, the Applicant respectfully submits that the combination of *Niazi*, *Gould*, *Williams*, and *Stevens* does not teach or suggest each and every element and limitation of independent claims 1 and 24.

Claims 3, 4, 32, 33 46-48 and 52-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Niazi* in view of *Gould* and *Williams* as applied to claim 1 and 24, and further in view of U.S. Patent No. 5,409,469 to *Schaerf* (hereinafter “*Schaerf*”). Claims 5, 6, 34 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Niazi* in view of *Gould* and *Williams* as applied to claims 1 and 24, and further in view of U.S. Publication No. 2001/0039413 by *Bowe* (hereinafter “*Bowe*”). Claims 7 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Niazi* in view of *Gould* and *Williams* as applied to claims 1 and 24, and further in view of U.S. Patent No. 6,533,770 to *Lepulu et al.* (hereinafter “*Lepulu*”). Claims 11-14, 40 and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Niazi* in view of *Gould* and *Williams* as applied to claims 1 and 24.

In each rejection of dependent claims 2-8, 11-15, 25-37, 40-42, 44-48, and 50-54, the Examiner relies on the combination of *Niazi*, *Gould*, and *Williams* to render independent claims 1 and 24 obvious, as well as the further combination of *Stevens* to render obvious the subject matter of claims 43 and 49, which was added to independent claims 1 and 24, respectively. The Examiner further relies on *Schaerf*, *Bowe* and *Lepulu* to teach or suggest the elements and limitations of dependent claims 2-8, 11-15, 25-37, 40-42, 44-48, and 50-54.

Each of claims 2-8, 11-15, 25-37, 40-42, 44-48, and 50-54 depend from one of independent claims 1 and 24. Independent claims 1 and 24 are not obvious for at least the reason that the cited references fail to teach or suggest each and every element and limitation recited in each claim, as discussed above. Furthermore, while the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 24. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 2-8, 11-15, 25-37, 40-42,

44-48, and 50-54 are not made obvious by *Niazi* in view of *Gould* and *Williams*; *Niazi* in view of *Gould*, *Williams* and *Schaerf*; *Niazi* in view of *Gould*, *Williams* and *Bowe*; *Niazi* in view of *Gould*, *Williams* and *Lepulu*; or *Niazi* in view of *Gould*, *Williams* and *Stevens*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-8, 11-15, 24-37, 40-42, 44-48, and 50-54 and notification that these claims are in condition for allowance.

Concerning, in particular, the rejection of claims 3, 4 32, 33, 46-48, and 52-54, the Applicant respectfully submits that no combination of asserted references makes these claims obvious in view of the amendments made to independent claims 1 and 24. The apparatus disclosed in *Stevens* does not appear amenable to separation with regard to its handle/actuator or catheter shaft. The handle/actuator of *Stevens*, for example, does not allow for physician implemented handle/shaft separation. Further, there is no teaching in any of the references that would allow for the proposed combination without either changing the principle of operation of the prior art being modified or rendering the prior art invention being modified unsatisfactory for its intended purpose. *See*, MPEP § 2143.01; *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). For at least these reasons and those discussed above with respect to the patentability of independent claims 1 and 24, the Applicant respectfully submits that at least claims 3, 4 32, 33, 46-48, and 52-54 are clearly not rendered obvious by the asserted combination of references.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of the Applicant's invention, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of

the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims and lack of motivation to combine reference teachings. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

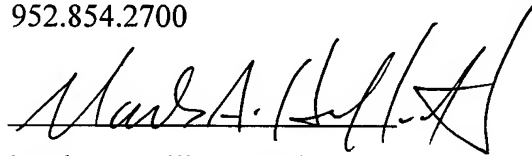
Authorization is given to charge Deposit Account No. 50-3581 (GUID.038US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

HOLLINGSWORTH & FUNK, LLC  
8009 34<sup>th</sup> Avenue South, Suite 125  
Minneapolis, MN 55425  
952.854.2700

Date: February 28, 2007

By:



Mark A. Hollingsworth  
Reg. No. 38,491